

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

RECKITT BENCKISER  
PHARMACEUTICALS, INC., RB  
PHARMACEUTICALS LIMITED, and  
MONOSOL RX, LLC,

Plaintiffs,

v.

ALVOGEN PINE BROOK, INC.

Defendants.

CA. No. 13-CV-2003 RGA

**REDACTED VERSION  
OF D.I. 52**

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS**

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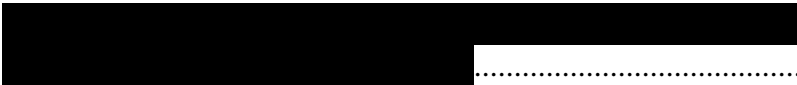
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Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. (“RBP”), RB Pharmaceuticals Limited (“RBP UK”), and MonoSol Rx, LLC (“MonoSol”) (“collectively, “Plaintiffs”), pursuant to Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 41(a)(2), respectfully request that this Court grant Plaintiffs’ Motion to Dismiss, without prejudice, all claims in this action against defendant Alvogen Pine Brook, Inc. (“Alvogen”) and all of Alvogen’s counterclaims against Plaintiffs.

## **I. INTRODUCTION**

Just last month, this Court, at the request of a plaintiff brand pharmaceutical company, dismissed without prejudice the plaintiff’s patent infringement suit under 35 U.S.C. § 271(e)(2) against the filer of an Abbreviated New Drug Application (“ANDA”) because the ANDA filer had prematurely served its Paragraph IV notice on the plaintiff without first having received an acceptance of filing letter from the U.S. Food and Drug Administration (FDA) that the ANDA was sufficiently complete for review, as required by the Hatch-Waxman statute, 35 U.S.C. § 355(j)(2)(B)(ii)(II). (Severance Decl.<sup>1</sup>, Ex. A [D.I. 24, Order, in *Otsuka Pharm. Co. Ltd. v. Par Pharm., Inc.*, No. 13-1979 (D. Del. March 10, 2014)].) Since the Paragraph IV notice was premature, untimely and ineffective, it failed to trigger the Hatch Waxman litigation process and therefore did not give rise to subject matter jurisdiction under 35 U.S.C. § 271(e)(2). (*Id.*)

[REDACTED]

[REDACTED]

[REDACTED] Therefore, all of Alvogen’s Paragraph IV certifications to Plaintiffs with respect to Alvogen’s subject ANDA were premature, untimely, and ineffective and, just as in *Otsuka*, failed to give rise to subject matter jurisdiction under 271(e)(2). Accordingly, all the claims in this action, including Alvogen’s counterclaims, should be dismissed without prejudice. *Id.*

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<sup>1</sup>The “Severance Decl.” refers to the Declaration of Dana K. Severance in Support of Plaintiffs’ Motion to Dismiss, filed concurrently.

## II. BACKGROUND

### A. The ANDA Litigation Process

Pharmaceutical companies must obtain approval from the FDA in order to market a new drug in the United States. This is typically accomplished through the filing of a New Drug Application (“NDA”). *See* 21 U.S.C. § 355(a); D.I. 23 [Amended Complaint (hereinafter “Complaint”)] ¶¶ 18-19. The NDA sponsor company must submit information to the FDA pertaining to all patents claiming the drug, or a method of using the drug, that is the subject of the NDA. 21 U.S.C. § 355(b)(1) and (c)(2). The FDA subsequently records that patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the “Orange Book.” *See* 21 U.S.C. § 355(b)(1) and (c)(2); Complaint ¶ 20.

When a generic drug manufacturer seeks to produce a generic version of a previously approved drug, the manufacturer must file an Abbreviated New Drug Application (“ANDA”) instead of an NDA. *See* 21 U.S.C. § 355(j); Complaint ¶¶ 21-29. Approval of a generic drug is abbreviated because the generic manufacturer is permitted to rely on the NDA sponsor company’s data as well as the FDA’s prior findings of safety and efficacy, which can be achieved, for example, by demonstrating that the generic drug is bioequivalent to the previously approved drug.

In addition to the abbreviated application process for generic drugs, Congress implemented a statutory process to resolve patent disputes between NDA sponsor companies and generic drug manufacturers, wherein the ANDA filer must provide specific certifications, known as “Paragraph IV Certifications,” for each patent listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12); Complaint ¶¶ 21-29. The ANDA filer may certify its belief that a patent is invalid or will not be infringed by the manufacture, use,

or sale of the generic drug that is the subject of the ANDA. *See* 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

After submitting an ANDA to the FDA, the FDA must preliminarily review the application within 60 days and notify the applicant that the ANDA is sufficiently complete—it is only at this point at which the ANDA is deemed to have been filed. 21 C.F.R. § 314.101. When an ANDA has been accepted for review by the FDA, the generic drug company must provide notice (“Paragraph IV Notice”) to the owner of the listed patent and the holder of the NDA for the reference listed drug. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95; Complaint ¶¶ 21-29. Paragraph IV Notices must detail the factual and legal bases for the generic company’s belief that the challenged patent is invalid and/or not infringed by the proposed generic drug. *Id.*

Federal regulations require that Paragraph IV Notices be sent *only after* the FDA has officially received the ANDA and deemed it sufficiently complete for review. 21 U.S.C. § 355(j)(2)(B)(ii); 21 C.F.R. § 314.95(b).

If, after receiving a timely Paragraph IV Notice from an ANDA filer, the patentee or NDA holder files a patent infringement suit within 45 days, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(2)(B)(iii); 21 C.F.R. § 314.107(b)(3); Complaint ¶¶ 27, 29. The 30-month stay is critical to companies like Plaintiffs, because it prevents extreme financial injury that could otherwise result from FDA approval of an infringing product before allowing time for an appropriate resolution of the infringement case. *See* 21 U.S.C. § 355(j)(2)(B)(iii).

Generic drug companies are highly incentivized to prematurely submit incomplete ANDA filings, given that the earliest ANDA filer may be granted 180 days of generic exclusivity, during which time other ANDA filers are prohibited from competing with rival

generic drugs. *See* 21 U.S.C. § 355(j)(2)(B)(iv). Premature filing, or prematurely notifying the NDA holder or patent owner, allows the ANDA filer the potential to market its generic drug much earlier than ordinarily allowed. *Id.* As such, improper notification unnecessarily obliges the NDA holder or patent owner to expend significant resources in support of an infringement suit that, if the ANDA were ultimately denied review by the FDA, would have been entirely unnecessary. Furthermore, an ANDA filer that has not received an acceptance for filing letter from the FDA as to its subject ANDA should not be allowed to reap any strategic advantage from having prematurely triggered the Hatch Waxman litigation process as a result of serving a premature, untimely Paragraph IV Notice.

Accordingly, one of the important protections built into the ANDA process is that a generic applicant may not send a Paragraph IV Notice until it “receives from the FDA an acknowledgement letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review.” 21 C.F.R. § 314.95(b); *see also* 21 U.S.C. § 355(j)(2)(B)(ii). This regulatory and statutory safeguard prevents the service of a Paragraph IV Notice based on an incomplete or insufficient ANDA which may trigger unnecessary litigation, provide an improper and unjustified strategic benefit to the ANDA filer, and prejudice both the innovator company and other ANDA filers whose rights to exclusivity may be compromised. Consequently, an ANDA applicant may not serve a Paragraph IV Notice prior to its receipt of the FDA’s letter notifying them that the subject ANDA is sufficiently complete and has been accepted for substantive review.

**B. To Date, Alvogen Has Not Received An Acceptance of Filing Letter from The FDA for Its ANDA**

Alvogen sent Plaintiffs Paragraph IV Notices dated October 25, 2013 and November 21, 2013, stating that Alvogen had submitted ANDA No. 20-5954 to the FDA under 21 U.S.C. §

355(j), seeking approval to engage in commercial manufacture, use, and/or sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual film, a generic version of Plaintiffs' Suboxone® sublingual film, before expiration of Plaintiffs' patents.<sup>2</sup>(Complaint ¶¶ 16-17, D.I. 30 [Answer] ¶¶ 16-17.) These Paragraph IV Notices further provided that Alvogen's ANDA No. 20-5954 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. (Complaint ¶ 16; Answer ¶ 16.)

Alvogen sent Plaintiffs another Paragraph IV Notice dated December 10, 2013,<sup>3</sup> stating that ANDA No. 20-5954 contains a Paragraph IV Certification alleging that the '514 patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in Alvogen's ANDA. (Complaint ¶¶ 19-20; Answer ¶¶ 19-20.) This Notice further states that ANDA No. 20-5954 seeks approval to engage in commercial manufacture, use, and/or sale of Alvogen's generic product before expiration of the '514 Patent. (Complaint ¶ 19; Answer ¶ 19.) Plaintiffs subsequently received additional Notices from Alvogen which were identical to the December 10, 2013 Notice. (Complaint ¶ 21.)

On January 24, 2014, Plaintiffs filed an Amended Complaint within 45 days of receiving Alvogen's December 10, 2013 Notice regarding the '514 Patent.

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<sup>2</sup>This action was originally commenced within 45 days of Alvogen's October 25, 2013 Notice. Before the suit was filed, Alvogen's counsel informed Plaintiffs' counsel that Alvogen had not received an acceptance of filing letter for its ANDA from the FDA. Plaintiffs commenced suit, however, in order to protect their rights, including with respect to obtaining the 30-month stay of FDA marketing approval for Alvogen's ANDA provided under the Hatch Waxman framework.

<sup>3</sup>The Notices, dated October 25, 2013, November 21, 2013, and December 10, 2013, are collectively referred to as the "Purported Notice Letters."



On February 28, 2014, Plaintiffs sent an interrogatory to Alvogen requesting information as to whether Alvogen had received an acceptance for filing letter (sometimes referred to as an “AFF letter”) for its ANDA. [REDACTED]

[REDACTED] (Severance Decl., Ex. B [Defendant Alvogen Pine Brook, Inc.’s Response and Objections to Plaintiffs’ First Set of Joint Interrogatories to Defendants] at Response No. 1.) [REDACTED]

### III. ARGUMENT

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a claim for lack of jurisdiction over the subject matter. *Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977). Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to the court’s subject matter jurisdiction. *Mayfair Wireless v. Celico P’ship.*, No. 11-772, 2013 U.S. Dist. LEXIS 124206, at \*8 (D. Del. Aug. 30, 2013). Facial challenges attack the complaint on its face. *Mortensen*, 549 F.2d at 891. Factual challenges, such as this challenge, attack the existence of subject matter jurisdiction in fact, and apart from any pleadings. *Id.* Because the trial court’s jurisdiction is at issue in a factual 12(b)(1) motion, “there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *Id.*

Federal Rule of Civil Procedure 41(a)(2) authorizes voluntary dismissal of a claim and provides: “[A]n action may be dismissed at the plaintiff’s request only by court order, on terms that the court considers proper. If a defendant has pleaded a counterclaim before being served with the plaintiff’s motion to dismiss, the action may be dismissed over the defendant’s objection

only if the counterclaim can remain pending for independent adjudication.” “When a plaintiff moves for a dismissal without prejudice under Rule 41(a)(2), the decision to dismiss with prejudice or without is left to the discretion of the court.” *Benitec Austl. Ltd. v. Nucleonics, Inc.*, No. 04-0174, 2005 U.S. Dist. LEXIS 22008, at \*3 (D. Del. Sept. 29, 2005). A Rule 41(a)(2) motion “will be determined after attempting to secure substantial justice to both parties.” *Id.* at \*4. In considering the legitimate interests of both parties, “the Court must bear in mind that a plaintiff’s motion should be granted absent substantial prejudice to the defendant.” *Id.*

**A. The Court Should Dismiss this Action without Prejudice since It Lacks Subject Matter Jurisdiction in View of Alvogen’s Improper Triggering of The ANDA Litigation Process**

The Purported Notice Letters that Alvogen has sent to Plaintiffs in regard to its subject ANDA have been improper, premature, untimely, void and ineffective because [REDACTED]

[REDACTED] Such notice letters are effective to trigger the ANDA litigation process under the Hatch Waxman statute *only after* the ANDA filer has received such a letter from FDA stating that the ANDA is sufficiently complete to permit a substantive review and that is been accepted for filing on that basis.

The timing for provision of a Paragraph IV notice by an ANDA filer is governed by 21 U.S.C. § 355(j)(2)(B)(ii)(I):

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph -- (I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed.

The corresponding federal regulation construing this provision provides:

The applicant shall send the notice required by paragraph (a) of this section when it receives from FDA an acknowledgment letter stating that

its abbreviated new drug application is sufficiently complete to permit a substantive review.

21 C.F.R. § 314.95(b). The directive is unambiguous—before sending a Paragraph IV Notice to the patent owner and NDA holder, the ANDA filer must receive acknowledgement from the FDA that its ANDA has been filed (*i.e.*, is sufficiently complete to permit substantive review).

The legislative history of the Hatch-Waxman Act reveals policy considerations articulated by both Congress and the FDA regarding the importance of timing of Paragraph IV Notices. “Congress did not intend that applicants be permitted to circumvent this notice requirement [proposed 21 C.F.R. § 314.95(b)] by filing sham ANDA’s or ANDA’s which are substantially incomplete.” *SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 507 (E.D. Pa. 2008) (citing 59 Fed. Reg. 50,338, 50,349 (Oct. 3, 1994) (quoting H. R. REP. NO. 98-857, at 24 (1984))) (internal quotations omitted).) The FDA expressed similar concerns:

To permit an ANDA applicant to provide notice [to the patentee] before FDA has determined whether the ANDA is sufficiently complete would be contrary to the legislative history because it would only encourage ANDA applicants to file incomplete or ‘sham’ ANDA’s and to supplement them later to secure a place in the review queue in an attempt to secure the first ANDA approval.

*SB Pharmco*, 552 F. Supp. 2d at 508 (citing 59 Fed. Reg. 50,338, 50,350 (Oct. 3, 1994)). In *SB Pharmco*, the generic ANDA filer sent Paragraph IV notices, before its underlying ANDA was accepted by the FDA for filing. The court cited correspondence from the FDA interpreting 21 U.S.C. § 355(j)(2)(B)(ii)(II):

Notice of paragraph IV certification submitted in an amendment or supplement to an ANDA is to be sent “at the time” the amendment or supplement is submitted to the agency. Section 505(j)(2)(B)(ii)(II). Notice in this context does not raise the same concerns about premature notice because the agency will have already determined under 21 CFR 314.101 that the application being amended or supplemented is sufficiently complete to permit review.

*SB Pharmco*, 552 F. Supp. 2d at 510 (citation omitted). The court also noted that reading the entire provision in its entirety,<sup>4</sup> “it seems clear that subparagraph (II) refers to an amendment to an ANDA for which the FDA has already acknowledged receipt.” *Id.* at 509 n. 4. The court interpreted 21 U.S.C. § 355(j)(2)(B)(ii)(II) to mean that notice be sent simultaneously with the amendment or supplement “only if the amendment is submitted for an ANDA that has already been accepted for filing.” *Id.* at 510. The court concluded that the ANDA filer’s Paragraph IV notice was not valid or timely under 21 U.S.C. § 355(j)(2)(B)(ii)(II). As a result of the invalid, untimely Paragraph IV Notice, the court dismissed without prejudice the patentee’s alternative counts of infringement and the defendant’s counterclaims. *Id.* at 511.

This Court recently came to the same conclusion and afforded the same relief in the *Otsuka* case. In *Otsuka*, Par Pharmaceuticals, Inc. (“Par”) admitted that it sent Paragraph IV Notices to Otsuka prior to the ANDA being accepted for review by the FDA. (Severance Decl., Ex. C [D.I. 23, Otsuka Reply in *Otsuka*, No. 13-1979 (D. Del. March 7, 2014)] at 1.) Since those Paragraph IV Notices were premature and invalid, failed to trigger the ANDA litigation process, and thus failed to give rise to subject matter jurisdiction, the Court dismissed without prejudice Otsuka’s patent infringement claims and Par’s declaratory judgment counterclaims. (Severance Decl., Ex. A; Severance Decl., Ex. D [D.I. 15, Otsuka Opening Brief in *Otsuka*, No. 13-1979 (D.

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<sup>4</sup>21 U.S.C. § 355(j)(2)(B)(ii) states:

(ii) Timing of notice. An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

Del. Jan. 16, 2014)] at 1, 15-16.)

This Court's ruling in *Otsuka* is fully consistent with the position of the FDA:

FDA has not interpreted [the amendment provision] to require or permit applicants who amend their applications before receipt of an acknowledgement letter to provide notice before learning whether their application has been determined to be sufficiently complete to be received. Rather, this provision applies only to amendments made after an ANDA has been received.

(Severance Decl., Ex. E [August 15, 2012 letter from the FDA], available at <http://www.hpm.com/pdf/blog/Par%20Premature%20Notice%20Ltr.pdf> (last visited April 16, 2014).) Concluding that the premature notification was invalid and did not trigger the 45-day litigation window or 30-month stay, the FDA explained its rejection of the ANDA filer's (Par's) reliance on the amendment provision as follows:

The requirement that the ANDA applicant wait to send notice until it receives confirmation from the FDA that the application meets the requirements for review (i.e., may be "received") ensures that the NDA holder and patent owner do not needlessly expend resources to initiate litigation with respect to an ANDA that is incomplete and therefore may not be reviewed by the agency. . . . The agency believes Congress did not intend that incomplete application submissions would trigger legal action by a patent owner or NDA holder and therefore we implemented this interpretation of the notice requirement.

(*Id.* at Ex. E at 1-2.)

Thus, none of Alvogen's Purported Notice Letters to date have been timely or valid or effective; all have been premature and ineffective to trigger the ANDA litigation process because

[REDACTED]

[REDACTED]

#### IV. CONCLUSION

Accordingly, in the absence of an effective Paragraph IV Notice this Court lacks subject matter jurisdiction over the claims in this ANDA litigation, and the same relief that this Court

afforded in *Otsuka* should be granted here. Plaintiffs' infringement claims against Alvogen should be dismissed without prejudice, pursuant to Rule 41(a)(2) and Alvogen's counterclaims should be dismissed without prejudice, pursuant to Rule 12(b)(1).

Dated: April 18, 2014

**Redacted Version: April 29, 2014**

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 18, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on April 18, 2014, upon the following individuals via electronic mail:

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